REMARKS

Claims 2, 3, 5, 6, 9, and 11-26 are pending in the application and are at issue.

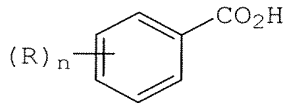
Claims 17 and 22 have been amended to recite that the hydric compound comprises dipropylene glycol, therefore excluding benzyl alcohol (an antimicrobial agent) from the claims.

THE INVENTION

The present invention is directed to a method of reducing a bacteria and/or virus population on a surface by contacting the surface with an antimicrobial composition. After 30 seconds of contact with the composition, the surface demonstrates a log reduction of at least 3 against *S. aureus* and/or *E. coli* (independent claim 17 and claim 18). The method also demonstrates antiviral activity (claims 19, 20, and 22-24). The surface can be animate (claims 21 and 24) or inanimate.

The compositions utilized in the claimed methods comprise (claim 17 and claim 22):

(a) about 0.1% to about 10%, by weight, of an aromatic carboxylic acid, wherein the aromatic carboxylic acid has a structure



wherein R, independently, is selected from the group consisting of hydroxy, C_{1-4}alkyl, C_{1-4}alkoxy, amino, halo, phenyl, and benzyl; and n is 1 or 2;

(b) about 10% to about 40%, by weight, of a hydric solvent comprising dipropylene glycol;

(c) a sufficient amount of a pH-adjusting compound to provide a pH of about 2 to about 5.5; and

(d) a carrier comprising water,

wherein the aromatic carboxylic acid is the sole antimicrobial agent in the composition,

and the composition contains 0% to 0.2%, by weight, of a surfactant.

Claims 2, 3, 5, 6, 9, 11-16, 25, and 26 recite more specific embodiments of the composition.

Some important features of the claimed composition are: (a) the aromatic carboxylic acid is the *sole* antimicrobial agent in the composition, (b) the composition contains 0% to 0.2%, by weight, of a surfactant, i.e., is essentially free of a surfactant, *and* (c) the composition contains a hydric solvent comprising dipropylene glycol. In claims 9 and 16, dipropylene glycol is the sole hydric solvent. As discussed below, the claimed compositions demonstrate unexpected results for a composition lacking a second antimicrobial agent and/or a surfactant.

Applicants particularly direct the examiner's attention to the examples in the specification. Specifically, Examples 1-3 show that pH is important to achieve efficacy (Ex. 1), that a hydric solvent alone is not efficacious (Ex. 2), and that an aromatic carboxylic acid alone, i.e., in the absence of a hydric solvent, is not efficacious (Ex. 3). By "not efficacious", it is meant that the claimed log reduction against *S. aureus* and/or *E. coli* of at least 3 after 30 seconds contact was not achieved. See the Declaration of Earl P. Seitz (Seitz Declaration, paragraph 17) filed concurrently with this response.

Example 4 of the specification illustrates that a minimum amount of hydric solvent is required to achieve the claimed log reduction of at least 3. As stated in the specification at page 25:

> "It is envisioned that a minimum amount of hydric solvent is needed in a composition to provide an AEI of at least 3, and this minimum amount is related to the identity of the hydric solvent, solution pH, and aromatic carboxylic acid concentration. The minimum amount of hydric solvent can be readily determined for any composition by the test criteria described in this example."

REJECTION UNDER 35 U.S.C. §103

Claims 2, 3, 5, 6, 9, and 11-26 stand rejected under 35 U.S.C. §103 as being obvious over Beerse et al. U.S. Patent No. 6,294,186 ('186). The examiner contends that the '186 patent renders the claimed methods obvious because the cited reference teaches compositions containing the same ingredients as the claimed compositions, and therefore are expected to provide similar characteristics. For the reasons set forth below, and in the Seitz Declaration, it is submitted that this rejection is in error and should be withdrawn.

THE CITED '186 PATENT

The '186 patent primarily teaches an antimicrobial composition containing a benzoic acid analog *and* a metal salt ('186 patent abstract). See '186 patent, column 3, lines 32-48. The '186 patent further teaches, explicitly, that the metal salt contributes to the antimicrobial activity. For example, the '186 patent states, at column 7, lines 60-65:

> "Without being limited by theory, it is believed that in the compositions of the present invention, the benzoic acid analog and metal salt complex to [sic] form a metal-acid complex which has been found to provide a synergistic immediate and residual anti-viral and antibacterial efficacy to surfaces to which such compositions are applied."

The '186 patent also contains 42 examples. Of these examples, 41 contain a metal salt as an antimicrobial agent *in addition to* the aromatic carboxylic acid.

The '186 patent also discloses a second embodiment wherein the composition contains a benzoic acid analog and a dermatologically effective carrier, and is essentially free of metal salts. See '186 patent, column 47, lines 18-54. The '186 patent contains one example (Example 21) that is free of a metal salt. However, the composition of this example also contains a total of 10 wt% of surfactants *and* 1.50% para-chloro-meta-xylenol (a second antimicrobial agent). The definition of dermatologically effective carriers in the '186 patent includes surfactants of the type disclosed in Example 21. See '186 patent, column 8, line 49 through column 9, line 3.

With respect to a hydric solvent, the '186 patent, at column 9, lines 33-54, discloses that a carrier for the disclosed composition can be an alcohol. The alcohol is broadly disclosed as monohydric and dihydric alcohols. Specific disclosed alcohols are monohydric alcohols, e.g., methanol. The sole disclosure of a dihydric alcohol, i.e., dipropylene glycol, is in Examples 16-18. In these examples, the amount of dipropylene glycol is 8%, by weight, which amount if present in a claimed composition, is insufficient to provide a claimed log reduction of at least 3. It also must be noted that Examples 16-18 of the '186 patent each include a metal salt, which is *excluded* from the present claims.

The other '186 patent examples referred to by the examiner, i.e., Examples 4, 12, 14, and 15 are free of a hydric solvent and contain a metal salt (which is excluded from the present claims).

NONOBVIOUS DIFFERENCES BETWEEN THE CITED '186 PATENT AND THE PRESENT CLAIMS

As stated above, and in the Seitz Declaration, the presently claimed method utilizes a composition that (a) contains an aromatic carboxylic acid as the *sole* antimicrobial agent, (b) contains an amount of hydric solvent to provide a log reduction of at least 3 against *S. aureus* and/or *E. coli* after 30 seconds contact, and (c) contains 0% to 0.2%, by weight, of a surfactant. The '186 patent fails to teach or suggest a composition having this combination of features.

The '186 patent explicitly teaches that the metal salt is an essential ingredient in one embodiment of the invention, and that the metal salt contributes to antimicrobial activity. In contrast to the '186 patent, the present claims *exclude* the presence of a metal salt that is taught as essential in the '186 patent. In particular, the claims clearly recite that the aromatic carboxylic acid is the *sole* antimicrobial agent in the composition.

In the second embodiment disclosed in the '186 patent, a metal salt is absent from a composition containing a benzoic acid analog and a dermatologically acceptable carrier. However, the sole example of this embodiment, i.e., Example 21, differs in *three* substantial ways from the present composition. First, although the composition of Example

21 is free of a metal salt as a second antimicrobial agent, the composition contains 1.50%, by weight, of the phenolic antimicrobial para-chloro-meta-xylenol (PCMX). See the '186 patent, column 20, line 34 through column 22, line 37, and especially column 21, lines 59-60. This phenolic antimicrobial agent is excluded from the present claims, i.e., it is *not* an aromatic carboxylic acid.

Second, a major carrier exemplified in the '186 patent in connection with this embodiment is a high (10 wt%) amount of surfactant (see '186 patent, Example 21). In contrast, the present claims recite a composition that contains 0% to about 0.2%, by weight, of a composition. Third, Example 21 of the '186 patent also is free of a hydric solvent, which is a presently claimed ingredient in an amount of about 10% to about 40%, by weight, of the composition, and which is required to provide a composition capable of providing an at least log 3 reduction in *S. aureus* and/or *E. coli* after 30 seconds of contact. The sole example of the '186 patent that is free of a metal salt therefore is completely different from a composition recited in the present claims.

The '186 patent also discloses that the carrier can be an alcohol solution, i.e., monohydric and/or dihydric alcohols. The preferred alcohols are monohydric C2-C18 alcohols, and the only specifically named alcohols are ethanol, isopropanol, n-propanol, butanol, and mixtures thereof. In contrast, the present claims recite at least 10% dipropylene glycol as the hydric solvent. Claim 9 is limited to dipropylene glycol as the hydric solvent. Although the '186 patent discloses dipropylene glycol in Examples 16-18, these examples each include (a) a metal salt and (b) the dipropylene glycol is present in too low an amount to provide an efficacious composition, as claimed, in the absence of a metal salt.

In contrast to the teachings of the '186 patent, the present claims recite a composition wherein an aromatic carboxylic acid is the *sole* antimicrobial agent in the composition *and* the composition contains 0% to about 0.2%, by weight, of a surfactant, i.e., is essentially free of a surfactant *and* the composition contains an amount of hydric solvent to achieve a log reduction of at least 3 against *S. aureus* and *E. coli* after 30 seconds contact.

At pages 3-4 of the Office Action, the examiner provides responses to applicants' previous arguments, and many of the statements show a definite hindsight

reconstruction of applicants' invention. In particular, the examiner has selected isolated teachings (i.e., ingredients or lack of ingredients) from different examples of the '186 patent to reconstruct applicants' claimed composition while *neglecting* other features present in the *same* example relied upon by the examiner.

For example, the examiner states at page 3:

> "The examiner contends that applicant's claims are bound by the transitional phrase of "comprising [sic] which permits the inclusion of additional components not specified in the claim. Moreover, as stated by applicant", Beerse et al do not require metal-salts in all of the embodiments and specifically suggest that the embodiments free of metal salts are effective in provide residual anti-viral efficacy (col. 47, lines 18-55) Therefore, Beerse et al do not require a metal-salt component as suggested by applicant, and further applicant's claims permit the use of additional ingredients not specified."

With respect to the contention that the term "comprising" allows additional components to be included in the composition, it must be pointed out that the claims specifically are limited to the aromatic carboxylic acid being the *sole* antimicrobial agent. Additional antimicrobial agents are excluded, e.g.., the metal salts taught in the '186 patent as antimicrobial agents. See Seitz Declaration, paragraphs 7, 12, and 15.

First, applicants did not state that the metal salt free embodiments of the '186 patent were efficacious. This is unknown to applicants. The sole embodiment is Example 21, which contains 10%, by weight, surfactant and 1.5%, by weight, of a second antimicrobial agent, and no efficacy data is provided in the '186 patent. The '186 patent may contend that the second embodiment of the disclosure is efficacious in the absence of surfactant and/or second antimicrobial agent, but has neither demonstrated such efficacy nor exemplified any such efficacious composition.

With respect to the examiner's comment that the '186 patent does not require a metal salt component, the only example free of a metal salt has both (a) 1.5 wt % of a second phenolic antimicrobial agent and (b) 10 wt % of a surfactant. Although the '186 patent at column 47, lines 18-54 suggests use of a benzoic acid analog in the absence of a metal salt, the reference *explicitly* teaches that a second antimicrobial agent is present to add to the

efficacy of the composition. Therefore, the phenolic antimicrobial agent present in Example 21 provides a boost in antimicrobial activity because the metal salt is absent. A presently claimed composition is *free* of both a second antimicrobial agent and a surfactant.

At pages 3 and 4 of the Office Action, the examiner further states:

> "Applicant argues that Beerse et al fail to suggest a surfactant having 0 to 0.2%; and 5 to 50% by weight of a hydric solvent.
>
> The examiner respectfully disagrees and directs applicant's attention to column 27, lines 55-60, which teaches less than 10% by weight of surfactants are needed. With respect to the hydric solvent, example 17 states 8% by weight of dipropylene glycol.
>
> Applicant argues that example 21 does not comprise a metal-salt but also does suggest high levels of surfactants."

First, the '186 patent at column 27, lines 56-59 actually states that *co-surfactants* are present at less than 10% by weight. Prior to this limited disclosure, the '186 patent discloses innumerable surfactants at columns 22-27, but fails to disclose any specific amount of amount of surfactant. The disclosure relating to co-surfactants relates to *additional* surfactants that *also* can be included. Accordingly, the examiner's reliance on column 27, lines 56-59 is misplaced. Moreover, the '186 patent fails to disclose a composition essentially (a) free of a surfactant, (b) free of a metal salt, *and* (c) free of a second antimicrobial agent. The examiner's reasoning is an example of hindsight reconstruction wherein an isolated statement is used to support a rejection without a consideration either of the claimed invention as a whole or the *complete* teachings of the reference.

In addition, Example 21 does not "suggest" high levels of surfactants. To be more precise, Example 21 *explicitly teaches* 5.0% ammonium lauryl sulfate and 5.0% ammonium laureth-3 sulfate, or 10.0% total surfactant, by weight. This is *50* times the claimed maximum of surfactant.

At page 4 of the Office Action, the examiner states:

> "The examiner contends that a reference does not need to teach each of the components in an example to be indicative of obviousness. The general teaching of Beerse et al states that metal –salt complex is not require [sic] to perform as suggested (col. 47, lines 18-55). Moreover, Beerse et al teach several embodiments that do not require surfactants (see examples 4, 12, 14-15, 16-18).
>
> A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill in the art, including nonpreferred embodiments. Merck & Co. v. Biocraft Laboratories, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989)."

The examiner appears to be saying that as long as individual ingredients of a composition can be found in a reference, then a claim can be found obvious. In looking at different embodiments of the '186 patent, the examiner is focusing on individual ingredients that may or may not be present, then adding the various ingredients together or deleting ingredients, to arrive at a conclusion of obviousness. The examiner has failed to consider the claimed invention as a whole, as opposed to its individual ingredients, and has failed to consider the unpredictability in the art, wherein changing the identity of an ingredient, or its actual or relative amount in a composition can substantially influence antimicrobial efficacy. For example, see the examples in the present application.

The examiner is "cherry picking" individual ingredients from various portions and examples of the '186 patent without considering either the entire teaching of the embodiments in the '186 patent or the claimed invention as a whole. The sole explicit teaching of a composition that is free of a metal salt in the '186 patent (Example 21) contains 10 wt % of a surfactant and 1.5 wt. % of a second antimicrobial agent, *both* of which are excluded from the present claims. The examples relied upon by the examiner all are free of a surfactant, but all *contain* a metal salt, which is excluded from the present claims.

In general, the examiner's reasoning also is inconsistent. To support exclusion of a metal salt, the examiner relies upon the limited general teachings of the '186 patent at column 47, lines 18-55, but neglects the specific teaching on Example 21. However, to support exclusion of a surfactant the examiner neglects the extensive general teachings at *columns* 22-27 of the '186 patent to include a surfactant, but relies upon specific examples to

exclude a surfactant. Overall, it is submitted that the '186 patent would *not* have *reasonably* suggested to a person skilled in the art to exclude a second antimicrobial agent *and* exclude surfactants *and* exclude a metal salt *and* include a sufficient amount of hydric solvent to provide a log reduction of at least 3 against *S. aureus* and/or *E. coli* after 30 seconds contact.

The examiner contends that testing against comparative examples is necessary to support patentability. However, applicants are not claiming an improvement over the '186 patent, but are claiming a method using an entirely different composition. The '186 patent contains no objective evidence of efficacy, but merely a definition of "residual antibacterial activity" at column 4, lines 22-39, and "Analytical Methods" at columns 44-46. However, even assuming *arguendo* that the '186 patent compositions are efficacious, comparing the present compositions to the '186 patent composition would serve little purpose. The compositions of the '186 patent arguably would be shown to be efficacious, and applicants already have shown that the claimed compositions are efficacious.

The present invention is a discovery that, contrary to the '186 patent, the claimed composition is efficacious in the *absence* of a metal salt, in the *absence* of a surfactant, and in the *absence* of any other second antimicrobial agent. The '186 patent fails to lead a person skilled in the art to make these multiple jumps in reasoning, and *then* include a sufficient amount of a claimed hydric solvent to provide the claimed log reduction of *S. aureus* and/or *E. coli* after 30 seconds contact.

More particularly, the present invention is demonstrated in the examples, wherein it is shown that an aromatic carboxylic acid or a hydric solvent *alone* does not provide a high antimicrobial efficacy, as claimed. Both the aromatic carboxylic acid and hydric solvent are needed to achieve a high antimicrobial efficacy, and a sufficient amount of the hydric solvent also is needed (see specification, Example 4).

In effect, applicants have provided comparative testing to the closest prior art. If one takes a composition from the '186 patent, and following the examiner's strained reasoning, then excludes the metal salt *and* a surfactant *and* any other second antimicrobial agent, the resulting composition would be those tested in Examples 1, 3, and 4. These examples show that simply excluding one or more of these components does not provide a

composition having the claimed efficacy. What is needed is a combination of aromatic carboxylic acid and a sufficient amount of hydric solvent, as claimed. It was the applicants that made the inventive discovery of including a hydric solvent in the claimed amounts to provide a highly efficacious composition for use in the claimed method. This discovery is neither taught nor suggested in the '186 patent.

The presently claimed invention clearly exhibits unexpected results, even when the essential metal salt of the '186 patent is omitted. In particular, the present examples show an unexpectedly high antimicrobial efficacy when both an aromatic carboxylic *and* a claimed hydric solvent are present (see Examples 1, 4, 7, and 9). Comparative Examples 2 and 3 show that both the aromatic carboxylic acid *and* hydric solvent are needed to achieve a high antimicrobial efficacy.

At page 5 of the Office Action, the "examiner contends that the general teaching of Beerse et al. states that the metal-salt complex is not require [sic] to perform as suggested". However, the only disclosure of the '186 patent supporting the statements at column 47, lines 18-54, is Example 21, wherein a second antimicrobial agent, i.e., PCMX, is utilized to enhance the antimicrobial activity of the benzoic acid analog. The substantial differences between Example 21 of the '186 patent and the present compositions are set forth above, and in the Seitz Declaration (paragraphs 7-16), showing that the comparison between a composition of the '186 patent and a claimed composition would be meaningless.

The differences between present claims and the '186 patent would not have been obvious to a person skilled in the art under 35 U.S.C. §103. In fact, the '186 patent fails to make the present claims *prima facie* obvious. Simply put, the '186 patent provides no apparent reason to modify the '186 patent as suggested by the examiner with any reasonable expectation of providing an efficacious antibacterial method. The '186 patent stresses the necessity of including a metal salt or other second antimicrobial agent in the composition in order to achieve an enhanced antimicrobial action. For example, the '186 patent includes 42 examples, of which 41 contain a metal salt as an antimicrobial component. The sole example in the '186 patent omitting a metal salt, i.e., Example 21, contains a high percentage of anionic surfactant *and* is lacking a hydric solvent *and* contains a second antimicrobial agent. The '186 patent fails to teach or suggest a composition that (a) omits a metal salt and other

additional antimicrobial agents, *and* (b) is essentially free of a surfactant, *and* (c) includes a hydric solvent, as presently claimed. From the teachings of the '186 patent, a person skilled in the art would not have been motivated to omit a metal salt *and* omit a surfactant *and* include a claimed hydric solvent with any reasonable expectation of providing a useful antimicrobial composition.

The establishment of a *prima facie* case of obviousness is set forth in the MPEP §2143 stating:

> **"2143 Basic Requirements of a *Prima Facie* Case of Obviousness**
>
> To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.
>
> The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)."

To establish a *prima facie* case of obviousness, *all three* requirements recited in MPEP §2143 must be satisfied: (1) the prior art reference or combination of references must teach or suggest *all the limitations* of the claims to those of ordinary skill in the art. See *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970) ("All words in a claim must be considered in judging the patentability of that claim against the prior art."); (2) the prior art relied upon must contain some suggestion or incentive, coupled with knowledge generally available in the art at the time of the invention, that would have motivated those of ordinary skill in the art to modify a reference or combine the references. See, *Karsten Mfg. Corp. v. Cleveland Golf Co.*, 242 F.3d 1376, 1385, 58 USPQ2d 1286, 1293 (Fed. Cir. 2001) ("in holding an invention obvious in view of a combination of references, there must be some suggestion, motivation, or teaching in the prior art that would have led a person of ordinary skill in the art to select the references and combine them in a way that would produce the

claimed invention."); *and* (3) the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made.

In the present application, the '186 patent fails to teach or suggest all the limitations of the claims to those of ordinary skill in the art, i.e., an aromatic carboxylic acid as the sole antimicrobial agent, the claimed amount of dipropylene glycol, and the claimed amount of surfactant.

The '186 patent also fails to provide an incentive to modify the teachings of the references and arrive at the present invention. The '186 patent has a limited disclosure that a metal ion can be excluded from the composition, but the reference fails to teach that an aromatic carboxylic acid can be used as the sole antimicrobial agent. The '186 patent explicitly teaches using a second antimicrobial agent when the metal ion is excluded. The '186 patent also teaches using a high amount of surfactant in the absence of a metal ion, and fails to teach dipropylene glycol in the absence of a metal ion. Also see Seitz Declaration, paragraphs 8-18.

The proposed modifications of the '186 patent to arrive at the present invention also would not have a reasonable expectation of success, as seen through the eye of a person skilled in the art. See Seitz Declaration, paragraph 18.

The '186 patent therefore fails to meet the criteria set forth as MPEP §2143, and accordingly, a *prima facie* case of obviousness has not been made and the rejection should be withdrawn.

In summary, persons skilled in the art simply would not be motivated make the several jumps in reasoning needed to arrive at the presently claimed invention after reading the '186 patent. Therefore, in view of the substantial differences between the '186 patent and the present claims, it is submitted that the rejection of the pending claims as being obvious over the '186 patent under 35 U.S.C. §103 should be withdrawn.

It is submitted that the claims are in proper form and scope for allowance. An early and favorable action on the merits is respectfully requested.

Should the examiner wish to discuss the foregoing, or any matter of form in an effort to advance this application toward allowance, the examiner is urged to telephone the undersigned at the indicated number.

Dated: July 25, 2008

Respectfully submitted,

By _____

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